5. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS (INITIAL – PRESCRIPTION GENERIC DRUGS)

This Certificate of Product Registration is granted to Marketing Authorization Holders of prescription generic drugs upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	**Initial Branded:** Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997). **2 year-validity:** Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF **Variation-turned-Initial:** Php 15,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF PHARMACEUTICAL PRODUCTS (PRESCRIPTION – HUMAN DRUGS) **ASEAN Common Technical Dossier** Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant

Sec. C Guidance on the Administrative Data and Product Information 1. Duly accomplished and notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) 2. Letter of Authorization (where applicable) 3. Certifications For contract manufacturing: a. License of pharmaceutical industries and contract manufacturer b. Contract manufacturing agreement c. GMP certificate of contract manufacturer For manufacturing "under-license" a. License of pharmaceutical industries b. GMP certificate of the manufacturer c. Copy of "under-license" agreement For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific) For imported products a. License of pharmaceutical industries/importer/wholesaler (country specific) b. Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format c. Foreign GMP Clearance 4. Site Master File 5. Labeling 6. Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) 7. Product Information a. Package Insert b. Summary of Product Characteristics (Product Data Sheet)	Company/Manufacturer (For the whole Part I) FDA Website & Cashier

Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 5 Reference Standards or Materials S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties	Applicant Company/Manufacturer (For the whole Part II): Quality Document

P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/equivalence evidence (if applicable) Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE (MR)/MONITORED RELEASE EXTENSION (MRE) TO INITIAL APPLICATIONS: 1. ACTD Parts I & II (same as above) 2. Risk Management Plan 3. Periodic Safety Update Report (PSUR) or Phase IV Clinical Study Report (whichever is	 Applicant Company/ Manufacturer Applicant Company/ Manufacturer

applicable) 4. Other post-approval commitments (if any, based on the Special Conditions at the back page of the CPR and accompanying letter)	Applicant Company/ Manufacturer
Additional Requirement for Dangerous Drugs (as per RA 9165 and Dangerous Drugs Board): -License to Handle Dangerous Drugs	Philippine Drug Enforcement Agency (PDEA)
Note: As per FDA Circular No. 2020-003, Submission of Risk Management Plan for a generic drug is not required, but it is expected that the Marketing Authorization Holder (MAH) will continue to evaluate the safety of their products on a regular basis and must be readily available upon request of FDA in case-to-case basis, such as but not limited to: • In response to a safety concern arising from a new route of administration; • As a result of a new safety concern associated with a new indication that may require additional PV activities; If the innovator or reference product has safety concerns that have been identified to require additional local PV activities.	Applicant Company/Manufacturer

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*

	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	3. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	Day 1 1 working day	FDA Cashier/ Landbank FDAC *Personnel*

	4. Receives the application from FDAC and encodes/updates the database	None	Day 2 1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and
	5. Queuing time of the application before decking to evaluators	None	Day 2-21 20 working days	CDRR-CRR Unit Personnel
	6. Decks/Assigns the application to the assigned evaluator	None	Day 22 1 working day	LRD *Chief*
	7. Evaluates the application according to requirements and prescribed standards	None	Day 23-72 50 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III

If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (for major deficiencies) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III

	8. Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	Day 73-112 40 working days	FDRO III
	9. Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III or higher) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR. For Dangerous Drugs, prepares a letter/notification to PDEA to seek comments/ recommendations on the application.	None	Day 113 1 working day	FDRO I/II
	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	Day 114 1 working day	FDRO III
	11. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	Day 115 1 working day	FDRO IV (Supervisor)

	12. Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	Day 116 1 working day (per batch of applications)	LRD *Chief*
	13. Signs and approves the final decision	None	Day 117 1 working day (per batch of applications)	CDRR *Director*
	14. Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the CDRR-Records Section	None	Day 118 1 working day (per batch of applications)	CDRR-CRR Unit *Personnel*
	15. Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	Day 119 1 working day (per batch of applications)	CDRR-Records *Personnel*
3. Receives the CPR/LOD/letter	16. Releases the CPR/LOD/letter to the client	None	Day 120 1 working day	AFS Releasing Section
(Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).		**TOTAL**:	**120 working days**	